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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,558	09/30/2003	Natarajan Ranganathan	KBI-0016	7898
7590	04/28/2005			
Licata & Tyrrell P.C. 66 E. Main Street Marlton, NJ 08053			EXAMINER DAVIS, RUTH A	
			ART UNIT 1651	PAPER NUMBER
DATE MAILED: 04/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/676,558	Applicant(s) RANGANATHAN, NATARAJAN	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03; 1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

RD

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 4 in the reply filed on February 25, 2005 is acknowledged. The traversal is on the grounds that the search for one group would overlap that of another group and since the limitations of group I must be searched to search group II, there is no burden on examiner. This is not found persuasive because while the searches for each group may overlap, an overlapping search is not a coextensive search. Furthermore, a reference that anticipates one group would not necessarily anticipate or even make obvious the other. Finally, while the method of group II requires the composition of claim 1, the composition of group I could be used in other materially different methods to include promoting immune function, promoting growth in livestock, treating diarrhea, and/or treating urogenital infections. Therefore the groups are considered both independent and distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claim 5 is withdrawn from consideration as being drawn to non elected subject matter.

Claims 1 – 4 have been considered on the merits.

Specification

2. The disclosure is objected to because of the following informalities:

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The claim for priority must include the current status of all applications to which the application claims benefit. Specifically, in paragraph 1 of page 1, application numbers 09/885,346 and 09/557,011 must include the issued patent numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cavaliere Vesely et al. (US 5716615 A), Morelli et al. (US 5709857 A), or Araki et al. (US 5741494 A).

Applicant claims a composition for enteric dialysis, the composition comprising a probiotic bacterium, which reduces urea concentration when ingested by a host.

Cavaliere Vesely teaches compositions comprising *Streptococcus thermophilus*, *Lactobacillus* and/or *Bifidobacteria* (probiotics which reduce urea when ingested) wherein the compositions absorb or reduce endogenous toxic substances (abstract, col.2 line 30 – 65).

Morelli teaches a composition comprising *Lactobacillus* (a probiotic which reduces urea when ingested) (abstract, claims).

Araki teaches compositions comprising *Bacillus*, *Lactobacillus* and/or *Bifidobacterium* species (probiotics which reduce urea when ingested) (abstract, col.1 line 35-65).

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Although the references do not teach the claimed function and use of the compositions, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore the references anticipate the claimed subject matter.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 – 4 are rejected under 35 U.S.C. 102(b)/103(a) as being unpatentable over Cavaliere Vesely.

Applicant claims a composition for enteric dialysis, the composition comprising a probiotic bacterium, which reduces urea concentration when ingested by a host. Specifically, the bacterium is *Streptococcus thermophilus* strain KB4, KB19, or KB25.

Cavaliere Vesely teaches compositions comprising *Streptococcus thermophilus* (a probiotic which reduce urea when ingested) wherein the compositions absorb or reduce endogenous toxic substances (abstract, col.2 line 30 – 65).

While the reference does not specifically teach the claimed strains of *S. thermophilus*, the composition of the prior art appears to be the same as that of the claim. Therefore the reference appears to anticipate the claimed subject matter. Even if the reference does not anticipate the claimed strains, then the claim is rendered obvious over Cavaliere Vesely, since the reference clearly teaches compositions comprising *S. thermophilus* which reduce and/or absorb endogenous toxins (or urea). Thus, it would have been obvious to one of ordinary skill in the art to use any strain of *S. thermophilus* in the composition of Cavaliere Vesely, with a reasonable expectation for successfully obtaining an effective composition for reducing endogenous toxins.

Although the reference does not teach the claimed use of the compositions, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the

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intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1 – 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5 and 13 of copending

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Application No. 10/803,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims merely require a probiotic bacterium, or a specific strain of *S. thermophilus*. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any strain, since the claims are to a generic *S. thermophilus*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1 – 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 8, 10 and 11 of copending Application No. 10/689,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims merely require a probiotic bacterium, or a specific strain of *S. thermophilus*. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any strain, since the claims are to a generic *S. thermophilus*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1 – 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 2 of copending Application No. 10/936,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims merely require a probiotic bacterium, or a

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specific strain of *S. thermophilus*. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any strain, since the claims are to a generic *S. thermophilus*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1 – 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6706287 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims merely require a probiotic bacterium, or a specific strain of *S. thermophilus*. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any strain, since the patented claims are composition comprising any probiotic.

13. Claims 1 – 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6706263 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims merely require a probiotic bacterium, or a specific strain of *S. thermophilus*. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any strain, since the patented claims are composition comprising any probiotic.

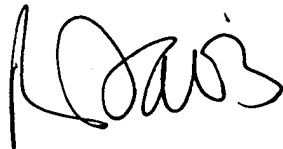
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
April 26, 2005
AU 1651

A handwritten signature in black ink, appearing to read 'R. Davis', is positioned to the right of the typed name and date.